

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

THE REGENTS OF THE UNIVERSITY OF
CALIFORNIA, ABBOTT MOLECULAR
INC., and ABBOTT LABORATORIES, INC.,

Plaintiffs,

v.

DAKO NORTH AMERICA, INC. and DAKO
DENMARK A/S,

Defendants.

No. C 05-03955 MHP

MEMORANDUM & ORDER

Re: Defendants' Motion in Limine

The Regents of the University of California, Abbott Molecular Inc. and Abbott Laboratories Inc. (collectively, "plaintiffs") brought this action against Dako North America, Inc. and Dako Denmark A/S (collectively, "Dako" or "defendants"), alleging infringement of two United States patents related to *in situ* DNA hybridization. In the course of ruling on the parties' motions in limine at the pre-trial conference, the court stated that it would consider one of Dako's motions further and issue an order. Having considered the parties' arguments fully, and for the reasons set forth below, the court rules as follows on the remaining motion.

I. Dako's Motion in Limine: Section VI and Sealey

Dako brings a motion in limine for an order precluding plaintiffs from presenting at trial, in defense to Dako's 35 U.S.C. section 112 invalidity claims, certain evidence relating to the effective

1 filing date of the one remaining patent in suit, United States Patent No. 5,447,841 (“the ‘841 patent”)
2 as well as certain material incorporated by reference therein. Specifically, Dako seek to preclude
3 plaintiffs from relying upon (a) Section VI of the ‘841 patent, the working example that was added
4 to the specification as part of a continuation-in-part (“CIP”) application on December 4, 1986, and
5 (b) the ‘841 patent’s incorporation by reference of a method in an article as follows: “The method is
6 generally described by Sealy [sic] et al., ‘Removal of Repeated Sequences for Hybridization
7 Probes,’ Nucleic Acid Research, Vol. 13, pp. 1905-1922 (1985), which reference is incorporated by
8 reference.” See ‘841 patent, col. 9:66-10:2.

9 A Precluding Plaintiffs from Relying on Section VI to Support Validity

10 With respect to the first issue, Dako clearly lays out in its moving papers that plaintiffs filed
11 the original “grandparent” patent application in a chain of applications leading to the ‘841 patent on
12 January 16, 1986; that plaintiffs are relying on January 16, 1986 as the effective filing date (i.e., the
13 priority date); and that Section VI was not added to the specification until December 4, 1986, when
14 the “parent” CIP was filed.

15 Against the backdrop of these relatively straightforward facts, the court finds Dako’s
16 arguments regarding what disclosure plaintiffs should be able to rely on and for what purpose rather
17 convoluted. In its papers, Dako contends that plaintiffs have asserted an effective filing date of
18 January 16, 1986 and plaintiffs “should be precluded at trial from relying on disclosures added to the
19 specification after that date to cure an inadequate written description and lack of enablement.”
20 Taken at face value, the court agrees with this statement insofar as plaintiffs may not rely on later-
21 added matter to support an earlier filing date. Plaintiffs agree they have alleged January 16, 1986 as
22 the priority date and that they will defend themselves against written description and enablement
23 invalidity challenges under section 112 based on the disclosure in the specification as of that date,
24 i.e., the disclosure of the original grandparent application. So far, the parties and the court seem to
25 be in agreement.

26 At the hearing on this matter, however, Dako pushed its argument further to contend that
27 plaintiffs should be precluded from relying on the working example of Section VI to support written
28 description and enablement at trial altogether. Dako argued orally that because plaintiffs asserted

1 during prosecution that the claims were entitled to the effective filing date of January 16, 1986,
2 plaintiffs cannot now argue for a later priority date to assert compliance with written description and
3 enablement. Dako hinges its argument on the rule that the same filing date must be applied for all
4 validity issues and, thus, plaintiffs cannot argue for a later date to satisfy section 112 while relying
5 on an earlier date to determine prior art and assert nonobviousness under 35 U.S.C. sections 102 and
6 103, respectively. This is where Dako begins to construct a straw man to attack.

7 It is true that all validity issues are determined as of the effective filing date for each claim.
8 Plaintiffs do not dispute this fact. Rather, plaintiffs assert that the first step in the jury's validity
9 assessment at trial is to determine the proper priority date for each asserted claim. Plaintiffs contend
10 they are entitled to argue validity based on whichever date the jury determines proper disclosure
11 exists for one or more claims. For example, if the jury determines the grandfather application
12 satisfies the requirements of section 112 for one or more claims at issue, then its filing date of
13 January 16, 1986 is the date upon which the jury will assess Dako's invalidity challenges for those
14 claims. If the jury determines the grandfather application does not satisfy the requirements of
15 section 112 for any asserted claim, but the parent application does, then December 4, 1986 is the
16 date the jury will assess Dako's invalidity challenges for the claims the jury has found are valid
17 under section 112 as of that date. In this way, all validity issues are adjudicated as of the effective
18 filing date. This is proper patent law procedure at trial and the court cannot imagine Dako doesn't
19 know this. "Whether the earlier applications enable the claims of the [patent-in-suit] is determined
20 as of the filing date of *each application*." Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254
21 (Fed. Cir. 2004) (emphasis added) (affirming a holding of invalidity because patentee did not
22 adequately disclose or support the subject matter of the patent-in-suit in any of its grandfather,
23 parent or issued patent applications).

24 At trial, a patentee is normally given an opportunity to demonstrate that its asserted patent
25 claims are supported by the specification of the patent-in-suit at any of the filing dates from which
26 the patent-in-suit claims priority. In Chiron, for example, the patent-at-issue had a filing lineage that
27 involved four different applications (three of which were CIPs) filed over a span of three years.
28 Because the parties had stipulated that the patent-in-suit would be invalid based on intervening prior

1 art if the patent were not entitled to claim priority to the filing date of *any one of* the 1984, 1985, and
2 1986 CIP applications, the thirteen-day jury trial adjudicated only whether *any of the priority*
3 *applications* satisfy the written description and enablement requirements of 35 U.S.C. section 112,
4 first paragraph. 363 F.3d at 1252. The Federal Circuit affirmed the finding of invalidity based on
5 the jury's determination that Genentech proved by clear and convincing evidence that none of the
6 applications satisfy both the written description and the enablement requirement for the subject
7 matter in the patent-in-suit's claims. *Id.* (noting that the verdict form did not require the jury to
8 specify the particular requirement of section 112 left unfulfilled by each disclosure of the priority
9 applications); *see also, Ariad Pharms, Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1374 (Fed. Cir. 2009)
10 (explaining that the question of priority was properly put to the jury and the jury was asked to
11 choose between two possible priority dates on the verdict form even though much of patentee's
12 evidence was directed to one date).

13 Dako's oral argument that plaintiffs should not be able to "have their cake and eat it too" by
14 asserting one priority date and then a later date to show written description and enablement amounts
15 to a fallacious shifting of the burden of proof. The '841 patent is presumed valid, such that plaintiffs
16 have the right to argue for one priority date without losing their right to argue for a later date. The
17 law places the burden squarely on Dako to prove by clear and convincing evidence that none of the
18 applications in the lineage of the patent-in-suit satisfies the requirements of section 112 for the
19 subject matter of the asserted claims. This is so even though plaintiffs have affirmatively alleged the
20 earlier January 1986 date as the effective filing date. Plaintiffs are only "estopped"—as contended
21 by Dako—from relying on disclosures added in the later-filed parent application to support written
22 description and enablement *for the earlier effective filing date*.¹ Plaintiffs may rely on Section VI in
23 the later-filed parent application to support written description for a later effective filing date, as
24 long as it is on or after the date that Section VI was added to the specification. Dako's reliance on
25 *Litton Sys. Inc., v. Whirlpool Corp.*, 728 F.2d 1423, 1439 (Fed. Cir. 1984) to suggest otherwise is
26 misplaced for several reasons, not the least of which is the fact that the CIP in that case contained no
27 later-filed disclosure (and thus, technically, did not constitute a CIP at all).

1 All of the other facts Dako presents about what else plaintiffs did during prosecution, e.g.,
2 filing a Rule 131 declaration to antedate an August 1985 article and asserting entitlement to the
3 grandparent application's filing date to the U.S. Patent and Trademark Office ("PTO"), do nothing
4 to affect this conclusion because none of those actions compels this court to find that a binding
5 judicial or evidentiary admission was made that precludes plaintiffs from arguing a later effective
6 filing date. See E.I. du Pont de Nemours & Co. v. MacDermid Printing Solutions, L.L.C., 525 F.3d
7 1353, 1358 (Fed. Cir. 2008) (holding that no binding admission was made to preclude patentee from
8 arguing an earlier priority date than the one patentee had previously alleged). As the Federal Circuit
9 articulated in PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299, 1305 (Fed. Cir. 2008), it can
10 be quite complex to determine the effective filing date to which each claim in a CIP application is
11 entitled. "In the absence of an interference or rejection which would require the PTO to make a
12 determination of priority, the PTO does not make such findings as a matter of course in
13 prosecution." Id. The court finds no evidence that a determination of priority for each one of the
14 asserted claims of the '841 patent was rendered by the PTO such that plaintiffs would be bound by
15 that determination at trial on a claim-by-claim basis.

16 Accordingly, to the extent that Dako's motion in limine sought to preclude plaintiffs from
17 relying on Section VI to support a priority date of December 4, 1986 at trial, that motion is
18 DENIED. For the sake of completeness, the court GRANTS Dako's motion in part, to the extent
19 that plaintiffs are only precluded from relying on Section VI to support the earlier January 16, 1986
20 priority date. Given that the grandparent application does not support the new matter added to the
21 parent application (and plaintiffs have never argued it does), it should come as no surprise that
22 plaintiffs cannot expressly rely on it to argue that the written description and enablement
23 requirements are satisfied for the earlier date. Finally, to the extent that a later priority date
24 determination would raise intervening prior art issues (or improper antedating issues), again, the
25 court notes that the burden is on Dako to raise such issues as part of its invalidity case under 35
26 U.S.C. section 102 or 103. See, e.g., Chiron, 363 F.3d at 1251-52 (reviewing the record for prior art
27 analysis application-by-application and considering the state of chimeric antibody technology and
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relevant publications at each respective filing date alongside the added disclosure in each application). In this way, the same filing date will be applied for all validity issues.

B. Precluding Plaintiffs from Relying on Sealey to Support Validity

As the second half of its motion in limine, Dako argues that plaintiffs should be precluded from relying on the blocking method disclosed in Sealey to defend against Dako's section 112 invalidity contentions. Dako argues that the incorporation by reference of the Sealey article is improper for two reasons: (1) "essential material" cannot be incorporated by reference through a non-patent publication and must be described in the patent specification, pursuant to 37 C.F.R. section 1.57(c), and (2) to incorporate material by reference, "the host document must identify with *detailed particularity* what specific material it incorporates." Zenon Env'tl. Inc. v. U.S. Filter Corp., 506 F.3d 1370, 1378 (Fed. Cir. 2007), citing Cook Biotech Inc. v. Acell, Inc., 460 F.3d 1365, 1376 (Fed. Cir. 2006).

Dako argues that because the blocking method in Sealey is necessary to provide written description or enablement, it is "essential material" and, as such, can only be incorporated by reference if it is a patent publication, which Sealey is not. Plaintiffs parry that Sealey is properly incorporated by reference as non-essential material. According to plaintiffs, the requirements of the regulation cited by Dako are inapplicable to the '841 patent because the '841 patent was filed, prosecuted and issued many years before 37 C.F.R. section 1.57(c) was promulgated by the PTO. Plaintiffs acknowledge that the PTO's Manual of Patent Examining Procedure ("MPEP") had a provision in existence at the time that limited the incorporation of essential material to patent publications. See MPEP § 608.01(p) (5th ed., 2d rev., Dec. 1985) (copy provided in Chang Dec., Docket No. 361, Exh. 2). However, plaintiffs contend that this provision, first, is not controlling, and second, provides for incorporation by reference of *non-patent* publications for *non-essential* material and thus Sealey is properly incorporated.

The court need not reach the impact, if any, of the cited regulation or the MPEP provision on the instant inquiry, because the thrust of plaintiffs' argument is that the method of Sealey is non-essential material that was well known to ordinary skilled artisans in January 1986 and thus can be relied upon to support written description and enablement of the '841 patent *regardless of the*

1 *manner in which it was incorporated by reference therein.* Plaintiffs also note that the issue of the
2 incorporation of Sealey came up during prosecution and the patent examiner accepted that the
3 incorporation was deemed proper based on the argument that Sealey was non-essential material.
4 According to plaintiffs, therefore, because a person of ordinary skill in the art in January 1986 would
5 reasonably understand and be aware of the blocking method disclosed in Sealey, that method was
6 properly incorporated by reference in the '841 patent.

7 Despite the circular-sounding nature of this argument, the court generally agrees with
8 plaintiffs that the method of Sealey constituted conventional technology that was well known to
9 those of ordinary skill in the art prior to the earliest filing date of the '841 patent. Accordingly,
10 Dako's assertion that the incorporation language in the '841 patent fails to meet the particularity and
11 location requirements enunciated in Zenon is unavailing. The relevant inquiry is whether the '841
12 patent incorporated by reference, with sufficient particularity to one reasonably skilled in the art,
13 what is included in the incorporated subject matter. See Advanced Display Sys., Inc. v. Kent State
14 Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000) ("the standard of one reasonably skilled in the art
15 should be used to determine whether the host document describes the material to be incorporated by
16 reference with sufficient particularity"). Whether and to what extent material has been incorporated
17 by reference into a host document is a question of law. Id.

18 The court finds that the method of Sealey was properly incorporated by reference in the '841
19 patent, considering that the Sealey document itself was in the prior art, the incorporation language
20 recited the full citation for the 1985 Sealey publication, and the '841 patent provided other
21 disclosure pertaining to that blocking method. The court draws a parallel to language cited by the
22 Federal Circuit as properly incorporating by reference a method described in an earlier publication,
23 which stated: "The preparation of UBS from a segment of urinary bladder is similar to the procedure
24 for preparing intestinal submucosa detailed in U.S. Patent No. 4,902,508, the disclosure of which is
25 expressly incorporated herein by reference." Cook, 460 F.3d at 1375. Although the Cook reference
26 was a patent publication (which goes to the "essential material" consideration, *supra*), the
27 incorporation standard for "integrating material from various documents into a host document" was
28 deemed to have been met with sufficient particularity to allow one reasonably skilled in the art to

1 apply the referenced procedure in the patent-at-issue. Id. at 1376-77. Based on this reasoning, the
 2 court finds the relevant disclosure of “the method . . . generally described in Sealey” as being
 3 incorporated with sufficient particularity to allow one reasonably skilled in the art to practice the
 4 Sealey method in the context of the ‘841 patent.

5 With respect to the “essential material” question, although the parties expended considerable
 6 time and energy on this issue, it is simply not for the court to make the determination of whether
 7 Sealey constitutes “that which is necessary to (1) support the claims, or (2) for adequate disclosure
 8 of the invention.” MPEP § 608.01(p) (5th ed., 2d rev., Dec. 1985) (defining “essential material”). It
 9 is a factual question for the jury to determine whether the Sealey method is necessary for adequate
 10 disclosure of the invention. Dako is incorrect that it is an all-or-nothing scenario, such that essential
 11 material is material needed to provide written description or enablement and non-essential material
 12 cannot provide written description or enablement. Were this the rule, there could be no requirement
 13 that a patent specification be interpreted by one of ordinary skill in the art, because all material
 14 supporting patent validity under section 112, which would include all relevant prior art, would need
 15 to be explicitly recited in the patent.

16 Thankfully for patent drafters, that is not the rule. The written description and enablement
 17 requirements of the patent laws do take into account the prior art, through the knowledge of one
 18 skilled in the art at the time the invention was made. For enablement law, see, e.g., In re Wands,
 19 858 F.2d 731, 737 (Fed. Cir.1988) (listing “the state of the prior art” and “the relative skill of those
 20 in the art” as two of the factors a court may consider in determining enablement); Chiron, 363 F.3d
 21 at 1254 (“A patent disclosure need not enable information within the knowledge of an ordinarily
 22 skilled artisan. Thus, a patentee preferably omits from the disclosure any routine technology that is
 23 well known at the time of application.”). For written description law, see, e.g., Ariad, 560 F.3d at
 24 1372 (“Whether the written description requirement is satisfied is a fact-based inquiry that is
 25 properly put to a jury, for consideration of such factors as the nature of the claimed invention and the
 26 knowledge of one skilled in the art at the time an invention is made and a patent application is
 27 filed.”) (citations omitted); PowerOasis, 522 F.3d at 1306-07 (explaining that section 112, paragraph
 28 1 “requires that the written description actually or inherently disclose the claim element”); Capon v.

1 Eshhar, 418 F.3d 1349, 1358 (Fed. Cir. 2005) (“The written description requirement must be applied
2 in the context of the particular invention and the state of the knowledge.”).

3 Accordingly, the court DENIES Dako’s motion and finds that plaintiffs are not precluded
4 from relying on the blocking method disclosed in Sealey to defend against Dako’s section 112
5 invalidity contentions. There is no inherent conflict between the notions asserted by plaintiff that
6 Sealey can be relied upon as prior art to support written description and enablement but nonetheless
7 cannot render the ‘841 patent obvious. The ‘841 patent does not claim the method of Sealey in and
8 of itself and a proper invention can certainly build upon prior art teachings. For example, in Capon,
9 the parties explained that the invention in question was “not in discovering which DNA segments
10 are related to the immune response, for that is in the prior art, but in the novel combination of the
11 DNA segments to achieve a novel result.” 418 F.3d at 1358. Likewise, here plaintiffs have made it
12 clear that the invention is not the blocking method itself, for that is disclosed in the prior art
13 (Sealey), but in the purportedly novel use of that blocking method in connection with *in situ*
14 hybridization to achieve the novel claimed methods of the ‘841 patent. Of course, whether the
15 blocking method of Sealey is needed to provide an adequate disclosure of the claimed methods of
16 the ‘841 patent remains a question of fact.

17 Having decided the questions of law raised by Dako’s motion in limine, the court leaves the
18 questions of fact raised herein for the jury.
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1 CONCLUSION

2 For the foregoing reasons, defendants' motion in limine to preclude plaintiffs from relying on
3 evidence to support written description and enablement is **GRANTED IN PART** and **DENIED IN**
4 **PART**. Dako's motion to preclude plaintiffs from relying on Section VI to support a priority date of
5 January 16, 1986 at trial is GRANTED. Dako's motion to preclude plaintiffs from relying on
6 Section VI to support a priority date of December 4, 1986 at trial is DENIED. Dako's motion to
7 preclude plaintiffs from relying on the blocking method disclosed in Sealey in defense to Dako's
8 written description and enablement claims is also DENIED.

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10 IT IS SO ORDERED.

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12 Dated: May 18, 2009



MARILYN HALL PATEL
United States District Court Judge
Northern District of California

ENDNOTES

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2 1. In fact, this is not a form of estoppel at all because the court cannot think of a situation in which a
3 patentee would be permitted to rely on later-added disclosure to support an earlier filing date,
4 irrespective of what patentee might have done during prosecution. This simple fact blows away Dako's
5 straw man argument concerning plaintiffs' lack of entitlement to use later-added matter to support an
6 earlier priority date. Plaintiffs have never sought to use Section VI to support their January 16, 1986
7 date. Plaintiffs merely request that they not be precluded from presenting evidence to support their
8 December 1986 date as an alternative effective filing date to the January 16, 1986 date.
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